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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,492	12/03/2001	Lawrence R. Toll	10454-017001	3231
26161	7590	09/29/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST. BOSTON, MA 02110			ALLEN, MARIANNE P	
			ART UNIT	PAPER NUMBER

1631

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/006,492

**Applicant(s)**

TOLL ET AL.

**Examiner**

Marianne P. Allen

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 41-75, 77-108, 111-140 and 142 is/are pending in the application.
- 4a) Of the above claim(s) 41-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 72-75, 77-108, 111-140 and 142 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 41-75, 77-108, 111-140, 142 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/22/04 has been entered.

Claims 76, 109-110, and 141 have been cancelled and claim 142 has been newly added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Election/Restrictions*

Claims 41-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 10.

### *Claim Rejections - 35 USC § 101/112*

Claims 72-75, 77-108, 111-140, and 142 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 72-75, 77-108, 111-140, and 142 are not originally filed claims. In the prior Office action applicant was requested to point to page and line number in the specification in

support of the steps and particular limitations of each claim. They have not done so. The claims have been amended to be directed to a statistical model comprising a hidden Markov model where a match state is characterized by a scoring matrix. However, the specification does not appear to disclose a method with the steps set forth. The method using the disclosed mHMM (the match Hidden Markov Model or integrated HMM) has specific steps not included in the claims, particularly the independent claims. (See in particular Figures 1-4.) The disclosed method identifies members of a family of biopolymer sequences that are characterized by a topological pattern of regions of similarity and dissimilarity. Modules that represent respective regions of a set of biopolymer sequences are linked to represent the topology of biopolymer. The modules are linked in an order that corresponds to the organization of the biological features. This is not what the claims describe. For example, the claims embrace linking modules in any order. For example, the modules are not required to reflect biological features. When constructing the model, the match state for each module is required to be one of similarity, dissimilarity, or matching to a profile as set forth in the specification. The match state is predicated on what is known or believed about the respective region (i.e. signal sequences should match a profile for a preprohormone, a known conserved region should require similarity for a preprohormone). The claims do not set forth these concepts. As presently written, the claims are ambiguous as to how many match states there are and/or what they represent and/or why the first match state defines a state of similarity or the second match state defines a state of dissimilarity. Note this is not with respect to an absolute number but rather with respect to the number of elements in the sequence that are of interest—signal peptide, cleavage site, etc. As written, the claims appear to require a similar and dissimilar match state that is arbitrary and is not based on

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the elements or regions of interest in the biopolymer. Once the particular model is constructed a given set of structured data objects can be compared to the model. Note that Figure 1 discloses determining the overall likelihood that a given set of sequences is represented by the model.

(See at least page 10, third full paragraph.) Note that the model outputs a score that represents this likelihood. (See at least page 13, fourth full paragraph.) This is not conceptually the same as “identifying the biopolymer sequences” as recited in the preamble and final step of the claims.

With respect to claim 142, while a computer-readable medium having stored instructions which cause a processor to perform method steps is seen, the concept of a “plurality of instructions including” these instructions is not seen.

Claims 72-75, 77-108, 111-140, and 142 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 72-75 and 77-106 are directed to a method for identifying biopolymer sequences comprising constructing a model, comparing the topological patterns and identifying biopolymer sequences. Claims 107-108 and 111-140 are directed to a method for identifying biopolymer sequences comprising constructing a model, comparing the topological patterns, comparing the scoring matrices for each match state, and identifying biopolymer sequences. Claim 142 is directed to a computer-readable medium having executable instructions.

As written, the claimed method recites only data manipulation steps and does not provide a concrete, tangible, and useful result. The claims provide no criteria for identifying biopolymers (i.e. if they are similar to the model identify them as being of interest) nor do the claims provide a tangible, concrete, or useful reason to identify the sequences (i.e. the method is

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intended to find sequences similar to something known to be useful because these similar sequences would be expected to be similarly useful.) As set forth in the prior Office actions, comparison alone does not result in identification of biopolymers.

Applicant is advised that a method of determining the overall likelihood that a given set of sequences is represented by the model or a method that includes a step of the model outputting a score that represents this likelihood would be considered a method that produced a concrete, tangible, and useful result. Applicant is cautioned against introducing new matter.

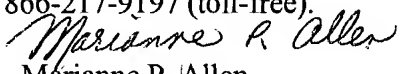
***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Marianne P. Allen  
Primary Examiner  
Art Unit 1631

9/27/04

mpa